

PRE-APPEAL BRIEF REQUEST FOR REVIEW

This pre-appeal request for review is submitted pursuant to 1296 *Off. Gaz. Pat. Office* 67 (July 12, 2005). Applicants have filed the required Notice of Appeal, fulfilling the obligations to have this request heard. In this application, Claims 30 – 37 are pending, and each claim stands rejected as unpatentable over Ginsburg, WO 00/10494 ("Ginsburg"), having a priority date for purposes of this case of March 2, 2000. Ginsburg is the only reference upon which the entirety of the pending rejections rely. Applicants request review because there is a "clear deficiency in the *prima facie* case in support of the rejection" at issue.

I. Applicants' Priority Date

The Final Office Action of November 5, 2009 failed to afford the correct priority date to Claim 30. Specifically, it is undisputed that if Claim 30 is supported by U.S. Serial No. 60/185,561 filed February 28, 2000, then Ginsburg is not prior art and the rejection cannot stand. It is also undisputed that Applicants are entitled to claim the benefit of the '561 application and all it discloses in the present application pursuant to 35 U.S.C. §120. The lone contention is whether Claim 30 is sufficiently supported by the '561 application. In particular, the Final Office Action states that "[Claim 30] recites that the controller varies the rate of heat exchange . . . as a function of the temperature differential between the current body temperature and the target temperature [and] this feature is not disclosed in the priority documents." [O.A., p. 2].

The standard for whether an invention is disclosed in a prior application is the first paragraph of 35 U.S.C. §112. **M.P.E.P.** §201.11(A) It must be remembered that "the subject matter of the claim need not be described *literally* (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." **M.P.E.P.** 2163.02 Furthermore, the law presumes that the description is adequate, and it is only when "sufficient evidence or reasoning to the contrary has been presented by the examiner" is the presumption rebutted. **M.P.E.P.** §2163.04 Accordingly, the examiner *must* present evidence of record "why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims" in order to overcome the legal presumption. *Id.* Without such evidence of record to overcome the application's presumption of adequacy of disclosure, Applicant is entitled to rely on the legal presumption affording Claim 30 the earlier filing date and the rejection based on Ginsburg is improper.

Despite the requirement of evidence as to why one of ordinary skill in the art would not have recognized the claimed invention, the totality of the Final Office Action's analysis is a mere, bald conclusion without support that the claimed feature "is not disclosed in the priority documents." This conclusory statement falls far short of the required analysis needed to overcome the presumption and establish a *prima facie* rejection. There is no discussion, much less evidence of record, offered as to: (1) what the Office Action considers the appropriate level of ordinary skill; and (2) why one of ordinary skill in the art would not recognize the claimed invention from the prior disclosure. Since it was the Examiner's burden to establish these elements, and the record shows there has been a complete failure to meet its legal burden, a *prima facie* case has not been met and the rejection is properly withdrawn.

Moreover, a review of the '561 application establishes that the written description requirement is indeed satisfied with respect to the features of Claim 30. At page 10, the reference states that the system measures a body temperature and a user enters a target temperature. The disclosure then states that the control unit "may actuate the TE cooler 11 to increase the amount of heat it is removing if the actual temperature is above the specified temperature . . ." Increasing the amount of heat **necessarily** *varies the rate of heat exchange*, and this rate of heat exchange is expressly described as a function of the difference between the current body temperature and the target temperature. It must be kept in mind that "by disclosing in a patent application a device that inherently performs a function or has a property, . . . a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it." **M.P.E.P.** §2163.07(a) There can be no dispute that increasing (or decreasing) the amount of heat based on the delta temperature is a variance of the heat exchange as a function of the temperature differential between target and actual. [Applicant further repeats and incorporates in full herein the arguments presented at pages 4-6 of the July 17, 2009 Amendment].

In view of the foregoing, it is evident that the disputed feature of the claimed invention in Claim 30 is clearly demonstrated in the '561 application, and therefore Claim 30 should have been afforded the filing date of the '561 application. At the very least, in order to overcome the legal presumption Applicant enjoys of an adequate disclosure and establish a *prima facie* case of lack of written description, it was incumbent upon the Examiner to provide reasoning as to why the skilled artisan would not have recognized the claimed invention from the '561 disclosure

and supported said reasoning with evidence of record. The failure to provide any reasoning or evidence in view of the obligation to do so and the clear and unambiguous disclosure in the '561 specification renders the pending rejection infirm and it is properly withdrawn.

II. The Anticipation Rejection

The rejection of Claim 37 is also improper because, even if the Ginsburg's priority date is not overcome, Ginsburg does not anticipate Claim 37.

It is black letter patent law that anticipation under 35 U.S.C. §102 requires identity of invention: the claimed invention, as described in appropriately construed claims, must be the same as that of the reference, in order to anticipate. Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1267, 20 USPQ2d 1746, 1748 (Fed.Cir. 1991); see also In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed.Cir. 1990) ("the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it"). Where the claim at issue is a method claim as is the case for Claim 37 here, "anticipation requires identity of the claimed process and a process of the prior art; the claimed process, including **each step** thereof, must have been described or embodied, either expressly or inherently, in a single reference." Scripps Clinic & Research Foundation v. Genetech Inc., 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991).

Claim 37 depends from Claim 30 and further recites the steps of "selecting a ramp rate equal to a desired time rate of change of temperature from the body temperature to the target temperature" and "setting the initial temperature of the catheter heat transfer region based on the selected ramp rate." This is supported in the specification at, *inter alia*, pages 28 – 30, as well as FIG. 8. In order to establish a *prima facie* case of anticipation, therefore, the Office Action must demonstrate that these steps are performed in the cited prior art in such a way as to show "identity of invention."

In the Office Action, the rejection of Claim 37 consists of but a single sentence: ". . . Ginsburg sets an initial rate and catheter temperature, and *inherently* adjusts the rate of heat addition/removal to maintain the desired rate." [O.A., p. 3] This is all that is proffered by the Office Action in its attempt to establish anticipation of Claim 37. It readily appears that the Office Action was unable to demonstrate an *expressed* teaching of the claimed steps, made evident by the fact that it points to nothing in the Ginsburg disclosure to satisfy its burden to show "identify of invention." Instead, the Office Action concedes that it relegated to reliance on

inherency in order to show that all the claimed features are taught by the Ginsburg reference. This purported rejection falls well short of that which is required to show inherency as a matter of law.

It is well established in patent law that inherency cannot be established by mere probability, or even a high likelihood. Rather, as the M.P.E.P. states, a rejection for an anticipation rejection would require in this case that the Office Action establish through evidence of record that Ginsburg's disclosure **necessarily** teaches the claimed steps. **M.P.E.P.** §2131 ("when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill"). Here, there is nothing in Ginsburg that teaches the step of "selecting a ramp rate equal to a desired time rate of change of temperature," or that Ginsburg's system is capable of such a step. To satisfy a *prima facie* case of anticipation, it was incumbent upon the Office Action to demonstrate, through evidence of record, that Ginsburg's system **necessarily** performs these steps, not that they *could* perform them or *might* perform them. If the Final Office Action is going to rely in inherency, as it concedes it must, then it is obligated to satisfy its burden to *prove* inherency and not merely state that it exists.

Applicant further contends that the Office Action has pointed to nothing in the Ginsburg reference that suggests it is capable of performing the claimed steps of Claim 37, much less that the steps are inherent. Selecting a rate of temperature change as claimed in Claim 37 is far different from merely using a PID controller as suggested by Ginsburg and cited by the Office Action. Unless the Office Action can establish that the PID controller of Ginsburg **necessarily** allowed the "selecting of a ramp rate . . ." and "setting the initial temperature of the catheter heat transfer region based on the selected ramp rate" with evidence of record, there can be no *prima facie* case of inherency or anticipation. For purposes of this pre-appeal review, the absence of any evidence establishing inherency and the complete failure to establish a *prima facie* rejection for anticipation warrants the withdrawal of the pending rejection of Claim 37.

Conclusion

Applicant has set forth grounds for why it would be unfair to force Applicant to expend the resources and time to go through the appeal process at this time. Ordinarily, because the present application enjoys the presumption of adequacy, the appeal process would normally be

reserved for addressing the sufficiency of the evidence proffered by the Office Action to satisfy its burden of proof as to why the written description is inadequate to support Claim 30.

However, since the Office Action offered no proof and no reasoning as to why the skilled artisan would not appreciate the claimed invention, Applicants are resigned to speculate what proof, if any, the Office will submit on appeal. If there is no evidence, then the appeal will be granted as a matter of law; and if there is evidence, it should have been proffered during the prosecution of this application so that Applicants would have a fair opportunity to address such evidence. Similarly, if the Office Action is relying on inherency to reject Claim 37, there must be a showing with evidence of record that the Ginsburg disclosure *necessarily* performs the claimed steps. This burden belongs to the Office Action *before* Applicants are required to offer a rebuttal. Since no evidence has been offered, the appeal process is premature and quite possibly unnecessary. Accordingly, Applicants respectfully request that the rejections of Claims 30 and 37 be withdrawn until such time as the Office has complied with its evidentiary burden so that if an appeal is ultimately necessary, the issues for appeal will be ripe and properly vetted in the prosecution phase of this case.

Respectfully submitted,

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